EXHIBIT E

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION — Master File No. 2:12-MD-02327 — MDL No. 2327

JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

Consolidated Trial
Mullins, et al. v. Ethicon, Inc., et al.
Case No. 2:12-cv-02952

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Debra Daniel, et al. v. Ethicon, Inc., et al. — Case No. 2:13-cv-02565

TELEPHONIC DEPOSITION OF MICHAEL WOODS, M.D., taken before Chelsey A. Horak, Court Reporter, General Notary Public within and for the State of Nebraska, beginning at 9:03 a.m., on July 28, 2016, at Regus, 1299 Farnam Street, Suite 300, Omaha, Nebraska.

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I N D E X

E X H I B I T S

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** Retained by Defense Counsel, Paul Rosenblatt

(Whereupon, the following proceedings were had, to-wit:)

MICHAEL WOODS, M.D.,
having been first duly sworn,
was examined and testified as follows:

DIRECT EXAMINATION

BY MR. BROWN:

Q. Good morning, Dr. Woods. My name is Greg Brown, and I represent the plaintiff, Debra Daniel. Do you understand that I'm going to be asking some case-specific questions regarding her case this morning?

A. Yes, I do.

Q. Okay. Thank you. If you have -- do you have your report in front of you?

A. The case-specific report --

Q. That's correct.

A. -- or the IME?

The case-specific report, yes, I do, sir.

Q. Okay. Thank you. And let's go ahead and mark your case-specific report for Debra Daniel as Exhibit 1, if you don't mind.

Sir, if you'll turn to -- I believe it's -- I think it's Page 9 of your report. I note that -- it looks like this report is dated -- it looks like June 15, 2015; is that correct?

MR. ROSENBLATT: Have her mark it.

THE WITNESS: One second. I'm having her mark that.

MR. BROWN: Okay. Sure.

(Exhibit No. 1 marked for identification.)

THE WITNESS: I'm now flipping through. And, yes, it is, June 15, 2016.

BY MR. BROWN:

Q. Okay. And my understanding is that you had the chance to conduct an IME, or independent medical exam, on -- it looks like -- my understanding is it was June 29, 2016?

A. That is correct.

Q. All right. Can we go ahead and mark the -- you do have a copy of your IME notes?

A. Yes, sir, I do.

Q. Let's go ahead and mark that as Exhibit 2, please.

(Exhibit No. 2 marked for identification.)

BY MR. BROWN:

Q. Since you have had the chance to conduct the IME on Ms. Daniel, have any of your opinions from your June 15 report changed in any way?

A. No, they have not.

Q. Okay.

All right. So if you'll turn back to Exhibit 1. I'll ask you about the IME in a bit, but I want to focus on your report for right now.

And I'd like to turn your attention to the first page. Are you with me?

A. Yes, sir.

Q. Okay. And you write that this is a summary of the medical records and deposition of Debra Daniel that were provided to me to review and offer a medical opinion concerning her claims of dyspareunia, pelvic pain, and voiding dysfunction that she claims are due to TVT retropubic placement and subsequent complication.

I understand that you had performed a differential diagnosis in Ms. Daniels case when forming your opinions; is that correct?

A. That is correct.

Q. And what do you define a differential diagnosis as, to begin?

A. A differential diagnosis would be various plausible causes of her conditions from a medical standpoint.

Q. Would you agree that to do a differential diagnosis, you need to first rule in possible causes of a condition?

A. I believe you need to look at possible causes and then go through a process to try and best process what would be the most likely causes of the condition, yes.

Q. So you would agree that you'd rule in potential causes and then subsequently rule out potential causes?

A. Correct.

Q. Okay. So my first question is: Did you perform a broad differential diagnosis for the totality of her alleged complications, or did you break each one down as a separate differential diagnosis?

A. Each area can have overlap, so you may have in one area a potential and also in another

area. You try to break them down, but there's oftentimes overlap.

Q. All right. Well, let me break down the complications that we see here in your report.

With respect to Debra Daniel's dyspareunia, what did you rule in as potential causes of this complication?

A. So what I'm going to do is refer to my case-specific report. And under the dyspareunia section, she had had dyspareunia documented as far back as 1997. After a pelvic reconstruction, which included a hysterectomy and retropubic TVT, she had had -- attempted intercourse about three times and experienced pain with each attempt. And so with that, you're looking at what could be the potential causes of postoperative pain with intercourse.

Also, the patient had stated at that time that her husband had become significantly disabled by his COPD and really was unable to have intercourse, and this was stated at the IME also.

So in looking at the potential causes of this, I would have to, one, look at is she menopausal or not, because we know that as women age and become menopausal, dyspareunia becomes a

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significant problem.

And we also know from studies from Weber and Francis, the Maher Cochrane reviews, and also ACOG -- I believe it's Committee Opinion 118, but I'm not positive on that -- that the incidence of dyspareunia is not uncommon, and it also is not uncommon after a hysterectomy with anterior and posterior colporrhaphy.

The patient is postmenopausal, and also in her history, she was noted to have adhesions at the top of the vagina at the time of her abdominal sacral colpopexy, and it's felt that adhesion may cause dyspareunia.

On my examination and also on examinations from the plaintiffs, we did discover that she had definite tenderness at the vaginal apex. And on my IME, what I did is I start off looking at possible areas that can cause pain with intercourse, because pain with intercourse can be insertional, it can be deep, and hers was described as deep.

So the first thing you do on the IME is I will have the patient walk and see if there's a gait dysfunction, could they have a shortened leg. I will do a soft-touch and pinprick exam of the

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perineum. I then will place one finger inside the vagina and check the muscle tone and if there is discomfort at the muscles of the opening of the vagina.

And in each of these with the patient, before we get started, I tell them -- whether it is an IME or a routine patient I see that has pelvic pain -- that my goal is to find out where the pain is coming from, and you need to tell me. And so what I will do is I will ask the patient, "Does this hurt? Is this uncomfortable? Also, does this replicate your pain," because sometimes, when you palpate, they may be uncomfortable, but that's not their pain and is more pressure from the exam.

So what I do is I go from the outside in. I look at the skin. Is it very thinned out from being postmenopausal? Can there be skin conditions that are associated with dyspareunia, such as lichen sclerosus or other dermatologic conditions.

I then exam the hymenal area to check the glands -- we call this the vestibule -- to see if they're inflamed, and I will take a Q-Tip, and I will touch these areas if there's any erythema and ask, "Is that your pain, and does it replicate your

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pain?"

After I pass the introital muscles, I then push over the rectum making sure that there isn't tenderness there that may indicate, especially in an older patient, possibility of diverticular disease or bowel inflammation.

I then go to the sacrospinous ligament, and I push on each side -- or each one of the ligaments seeing if that elicits pain, because if there's a tendinitis, that can replicate their pain. And each time I'm trying -- and I'm asking the patient, "Is this your pain? Does it replicate your pain," and continue that process.

At that point, I then check under the urethra to see if there is pain there that could indicate a diverticulum or urethral problems or even urethritis. I then gently palpate the bladder, and at this point, I'm looking for pain such as painful bladder syndrome or trigonitis or bladder etiology.

I then go deeper -- in her case, she's had a hysterectomy -- and I will gently touch the very lateral or side aspects of the vaginal cuff and apply pressure and see if that elicits their pain. I then will do a deeper exam trying to check the

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anexa [phonetic], and then if they're not having pain at that point, applying general pressure to the top of the vagina.

At that point, I then do a speculum exam and note if there's atrophy, what the vaginal supports are, but I also will take a Q-Tip and recheck areas, especially if there was any tenderness.

Specifically on her IME, she was tender on the right side. And when I asked her at that point, "Does this replicate your pain," she said, "Yes."

"Does it replicate your pain that you remember from intercourse?" She said, "Yes."

So on placing the Q-Tip -- on gentle placement of the Q-Tip in that area, I just did gentle pressure, and she said, "That is my pain," and that's how I did on the differential there on trying to figure out the location of the pain.

So what I'm looking at is bladder etiology, muscle etiology, tendons, rectal, hypersensitivity, and I try to go the length of the vagina with the idea of trying to figure out exactly where the pain is coming from.

Q. All right. Well, you said, obviously, a

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pretty decent amount. I just want to break a few things down.

With respect to her menopause, do you have any objective finding or did you see any objective finding in Ms. Daniel's medical records that indicate the fact that she's menopausal would be contributing to her dyspareunia?

A. The fact that she was menopausal and also was noted to have agglutination of the labia, suspicious for lichen sclerosus, that was a concern. And that was from, actually, Dr. Carey's exam.

And on my examination, she was very significantly atrophic. The speculum I had to use, something that we'll call a virginal speculum -- it's a small Pederson speculum -- just because the tissues were so easily friable, so very, very atrophic.

Q. So if I understood you correctly, what you're saying is that she had atrophy as a result of menopause, which then, in turn, is contributing to her dyspareunia? Is that what you're -- is that a fair summation of your opinion?

A. That is very well documented in the literature and even on -- from American College of

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Obstetrics and Gynecology bulletins, yes.

Q. Well, I appreciate about the general literature, but I'm asking about Ms. Daniel's specific case.

Is your opinion that the fact that she is menopausal and has atrophy, is that what you believe is a contributing factor to her dyspareunia?

A. Not only just the atrophy, but the atrophy indicates that in a prolonged menopausal state, the connective tissue changes composition over time, the blood supply to the vagina decreases over time, and also the vaginal ecosystem changes.

So the atrophy indicates that you have a significant amount of other changes that are going on within the pelvic floor and the vagina.

Q. All right. So let me ask you: I see this part of your report that says it is more likely than not that her anterior/posterior repairs, her pelvic organ prolapse symptoms, her ASC repair, and her vaginal atrophy and pelvic adhesive disease are the more likely causes of her reported of dyspareunia.

Have you been able to rule any of the above out as a potential cause of her dyspareunia?

MR. ROSENBLATT: Hey, Greg, do you

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want to tell us what page you were reading from?

MR. BROWN: Yeah. It's on Page 7. I think he had gone over a lot of that. It's on Page 7, first paragraph, on his case-specific report.

THE WITNESS: Is that the part, "I also considered tissue ingrowth...," or -- I'm not -- which paragraph is it, please?

BY MR. BROWN:

Q. Well, it's the first paragraph --

A. Okay.

Q. -- but it's the part where you're reading on the dyspareunia section of your differential diagnosis. And I'm asking on the -- it looks like the next -- it's on, I think, the next to last sentence in the first paragraph on Page 7.

A. Okay.

Q. Are you with me?

A. Yes, "I believe to a reasonable degree of medical certainty..." So --

Q. No, no, no. It's actually the one after that. It says, "It is more likely than not..." Okay. Well, I see what you're saying. Okay.

A. So it is more likely than not that her

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anterior and posterior repairs, which according to the literature have over -- can have over a 20 percent incidence of dyspareunia, would more likely than not be the cause of her pain. Also with the vaginal atrophy and the incidence of dyspareunia just with aging increasing significantly that we feel is due to atrophic changes, changes in the composition of the connective tissue, also can attribute to her dyspareunia, which she has both.

We also with the A and P repair and when she was noted to have vaginal shortening, this is common with A and P repairs. So each of these areas increased the incidence of dyspareunia, and her dyspareunia was described as deep.

And for me, when I was doing my examination, where she said it exactly replicated her pain was at the vaginal cuff, which is a significant distance from where the TVT was placed, and she really was not tender, and any palpation underneath the urethra or to the vaginal side wall, which would be the trajectory of the TVT, did not elicit or replicate the pain that she was complaining of.

Q. I understand, but what I'm asking is:

With this list of, you know, potential causes here, have you been able to rule any of these out as a potential cause of her dyspareunia?

A. I believe that she had lysis of adhesions at the time of her abdominal sacral colpopexy.

However, she did not really have intercourse after that, so it would have been nice if I would have been able to say it persisted or not from this because the lysis adhesions may or may not have helped.

So I could not rule out the lysis of adhesions as either a factor or not a factor in this case.

Q. Okay. Well, have you been able to -- aside from the lysis of adhesions, on this list of conditions in your report, have you been able to rule any of these other conditions out as a potential cause of her dyspareunia?

A. On the general atrophy, she was not tender at the introitus. However, the introitus, due to atrophy, was small, but she was not tender along the skin on examination.

So the external atrophy, I do not feel, because it was not insertional, was a cause.

However, the internal atrophy and the shortening of the vagina, I could not exclude.

Q. Okay. Let me ask you: When you're saying it's more likely than not that these conditions are the cause of her dyspareunia when compared to the TVT, have you ruled out the TVT as a potential cause of Ms. Daniel's dyspareunia completely, or is it just less of a possibility than this list?

A. I believe on my exam I could not replicate her pain anywhere along the TVT site or even in the upper third of the vagina, and with that in mind, I feel that the TVT was not the cause of the dyspareunia.

Q. So is it fair to say you ruled out the TVT as the cause of Ms. Daniel's dyspareunia completely?

A. Yes.

Q. All right. Let me turn to the next part of your differential diagnosis. Did you -- and you'll have to direct me to -- if you want to refer to your report.

With respect to Ms. Daniel's pelvic pain, tell me what you ruled in as potential causes of her pelvic pain in your differential diagnosis.

A. In my differential diagnosis -- in

one moment here, I'm going to be going -- in my differential diagnosis with the pelvic pain, again, we're going to be looking at her surgery. I also would have to consider does she have back injuries, does she have a gait defect, does she have hypertonic muscles, is there a history of sexual abuse or rape, also is there a history of endometriosis, chronic bladder pain.

Q. Well, and you're talking about a general differential diagnosis for a cause of pelvic pain, right?

A. Correct.

Q. I'm asking more specifically for Debra Daniel. Did you have objective findings in her medical records of any of what you just talked about?

A. Again, on the IME from Dr. Carey, she specifically pointed to the cuff tenderness, and, again, on my exam, that cuff tenderness exactly replicated her pain.

So with that in mind, I am looking at the vaginal apex, and so she's had an apical suspension, she has had a uterosacral colposuspension, along with the anterior repair, and with these, the

incidence of dyspareunia is significantly higher. Also, we do see pelvic pain.

It would have been nice if I would have been able to do such as a trigger-point injection to that area to see if that helped, but that was not done.

But on palpation of that area, that replicated not only her dyspareunia, but her pelvic pain, and she said it exactly replicated, so the problem is arising at that vaginal cuff on that right side.

Q. Okay. So fair to say that, you know, during your IME -- and that was after the report -- you were able to, as you say, replicate her pain, and you observed some cuff tenderness.

What I'm asking is: For Ms. Daniel's case-specific case, did you see a variety of things in her medical records as potential causes of her pelvic pain?

A. In her history of -- and I'm going to be referring to Page 1 -- and, by the way, there's a typographical error on there. It should say "with a past medical history of Raynaud's disease," not "over announce disease," so I apologize on that.

Q. Okay. So is that a potential cause of her pelvic pain?
A. No, I do not believe so. I just noticed that typo there.
Q. Okay.
A. She does have a history of irritable bowel syndrome, which can definitely be a cause of pelvic pain. She did have the atrophic vaginitis documented, and she had had dyspareunia in the past.
So as we're looking at all this, she's had some of these concerns. She's also had some back complaints. And she -- such as in 2007, on the bottom of Page 2, she had low back pain, urine was negative, and she was given ibuprofen.
She has a history of working in the construction industry doing a lot of heavy lifting, and, you know, so I have to consider is the idea -- is there back problems and things along those lines. And then --
Q. So the list you just talked about, the atrophic vaginitis, the irritable bowel syndrome, and then some complaints about lower back pain, were you able to rule any of those conditions out as a potential cause of Ms. Daniel's pelvic pain?

A. I believe that the atrophic vaginitis, that is probably not going to be a cause of her pelvic pain. It may be with the dyspareunia, but not necessarily the pelvic pain.
The irritable bowel syndrome can be associated with it, but she was not complaining of any pain at the IME, and I could not replicate that on palpation of the rectum or on rectal exam.
I did not do any imaging of her back or anything. She had presented with back pain also again in 2010, but she was not complaining of back pain at that time. You can have referred pain from the back to the pelvis, but I did not feel that that was going on at that time.
Q. Let me ask you: When you remarked that she had a prior history of dyspareunia -- and I'll get to her medical history in a bit, but are you aware of whether that dyspareunia was an episodic bout of dyspareunia, or was it chronic dyspareunia?
A. Actually, at that point, it was episodic, and I believe that that was shortly after she remarried. I'm trying to find --
Q. It looks to me like on Page 2 of your report, you had -- you remark in December 1997 that

she had a bout of painful intercourse that had resolved by looks like a week later or so, right?
A. Correct.
Q. Okay. So aside from that, the findings in 1997, did you see any other objective finding of dyspareunia, whether it be episodic or chronic, in her medical records prior to her TVT implant?
A. I believe that was the only time I saw in her medical records that she was complaining of dyspareunia.
Q. Well, let me ask you: In terms of her dyspareunia and her medical history, would you agree that it's a possibility that in 1997, she had episodic dyspareunia and now has a different more chronic dyspareunia as of today?
A. I believe her dyspareunia is different today. However, she's not been sexually active for several years now, and so I can't say what dyspareunia she's having today. I'd have to go by the history because of her husband's medical condition.
Q. Right.
All right. Well, let me turn -- let me return to the differential diagnosis with respect to

pelvic pain.
Have you -- in terms of what is more likely a cause of her pelvic pain -- and you gave me a list of IBS, atrophic vaginitis, and that she had also some back complaints and lower back pain. In your opinion, are these more likely the cause of her pelvic pain, rather than the TVT?
A. Yes. And more specifically, with the hysterectomy and pelvic reconstruction, we know that that can be associated with that. So I'm leaning much more towards the pelvic reconstruction and hysterectomy aspect as definitely a part of it.
Q. Well, have you ruled out the TVT as a cause of Ms. Daniel's pelvic pain completely, or is it that these conditions are more likely a cause?
A. I could not replicate her pain anywhere where the TVT was located. The origin of her pain is at the very top of the vagina, which is nowhere near the TVT, and it's very point specific. So more likely than not, the TVT is not the cause, and I have essentially felt very comfortable in ruling that out.
Q. So, in your opinion, a very small possibility that it's a cause, the TVT on her

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pelvic --
A. It's always a possibility. However, it's a possibility I could have a meteor come in and destroy the room right now. So it's always a possibility, but very highly unlikely.
Q. All right. Let me move on to your differential diagnosis with respect to her voiding dysfunction.
Tell me what you've ruled in as potential causes of Ms. Daniel's voiding dysfunction in your differential diagnosis.
A. In the differential diagnosis -- and, excuse me, I'm going to look through initially here.
Q. Go ahead.
A. When she had her surgery, she did have urinary retention, which is not uncommon more specifically with A and P repair. With TVT, you can see it, but in my own personal practice, when I do an A and P repair with either a Burch or a TVT or whatever, there is a higher incidence of urinary retention. And --
Q. Just -- I'm not trying to interrupt you, but when you say "her surgery," you're talking about her hysterectomy and TVT implant surgery?

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A. Hysterectomy and A and P repair and the suspensions. Hysterectomy and A and P repair are very vastly different, complex surgeries, so they -- I tend to sit back -- the incidence of urinary retention after a hysterectomy is variable. In my own personal experience, it's about 1 percent. However, with A and P repair, it is very significant for a day or two and up to about six weeks, depending on if you do, like, a Burch or something like this.
So when I'm looking at something along this line, if somebody had a straightforward hysterectomy and had urinary retention after a retropubic TVT, say, I would be leaning much more towards the TVT because we know that's not uncommon.
What was interesting specifically with this patient, and she discussed this at the IME, she asked -- because her biggest complaint before her TVT was actually urinary urgency, urinary frequency, and urgency incontinence, and in talking with her and we reviewed over her medical records, she did agree that she would be voiding 14 to 16 times a day and be up a couple times at night. She said that was her biggest problem. And then I explained to

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her at that time that the TVT is not designed to treat urgency incontinence.
Her next question to me was then why was the TVT done, and I said I'm not Dr. Sze, however you also complained of stress incontinence, and when we do a pelvic reconstruction, if a patient has stress incontinence beforehand, they have a much increased risk of having it worse after the surgery.
So on her history -- and I'm not Dr. Sze -- I said I could understand why he would place the TVT, and she then told me, "I've never had anybody explain that to me."
And then I asked her, "You're still having the urgency?"
And she said, "It's probably worse now than it was before the surgery," and then her follow-up question is was that the TVT.
And I did discuss with her that the de novo urgency with any bladder suspension, whether it be Burch, autologous sling, or TVT, can have an increase in de novo urgency. Some people actually it gets -- the urgency gets better, but that's not an expectation.
But also with time and menopause, urgency

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also gets worse, and we discussed actually that in detail, and I actually made some recommendations when she went home on what to ask, some questions of her provider there.
So with her urinary symptoms, you have to think is it TVT related, is it her A and P repair related, does it precede the surgery, and also what neurologic evaluation has been done. I reviewed over with her Dr. Sze's exam and kind of explained it to her. She said that no one had really explained what the findings were.
So we went over it. We talked about the Q-Tip angle change and that that was a little bit more mobile. I actually had some drawings of what was provided to her and that that should be what was sent with you. I'm not an artist by any stretch, but I tried to explain to her what was going on through the drawing so she could understand that.
And, you know, she had a positive stress test, and so I explained to her that thought process, and she still said that her biggest problem was the urgency, and she thought that was going to be taken care of.
So I'm really hopeful -- when I have a

patient come in, and even if it's an IME, I'm a doctor first and a patient first, and my goal is to educate the patient. So I'm trying retrospectively to kind of explain this series to her, and she had several questions on that.

So at the time of the IME, I then tried to explain to her I was not the surgeon doing it, but what was involved with the hysterectomy and the reconstruction. And, you know, she did have urinary retention postoperatively and then was able to pass a voiding trial and appeared to be better at that point.

She did follow up with Dr. Sze, and we reviewed over some of these records. And I specifically had the records out, you know, and I said, "Do you have any questions about this," and if she did, we'd try to answer them.

But in going through on the differential of her voiding dysfunction, she did have urgency, frequency, and urgency incontinence before her index surgery, and this definitely persisted afterwards.

She then had a recurrence of her prolapse and at that time underwent urodynamic studies, and we went over that. And then she asked that if

she -- when the suspension was done, kind of what was done in that, and I went over that with her.

But we did go over her cystometrogram and her urodynamics that were on July 10, 2015, so I tried to explain to her what this meant, and it also meant that her bladder at that time emptied slowly.

Dr. Shapiro felt that because the top of the vagina was prolapsing down, that the urethra was -- or the bladder neck was getting kinked, and this was probably the reason for the low flow. But her bladder capacity was essentially normal.

I then reviewed over with her Dr. Zaslau's on the cystoscopy and that it was reported as normal. And then we went over her postoperative course, and I tried to explain what all was -- what all was there, and I tried to specifically answer any of her questions on that line.

When we finished the IME -- I'm in a rural area, and she had to get back up to Omaha, and I drove her back, and her last question with me, it was, "Dr. Woods, did the TVT cause my -- does it cause my pain?"

And I looked at her, and I said, "No, it did not. The pain is away from there."

And she thanked me. She said, "No one has explained it to me."

So with her, I went through the differential diagnosis, in going through the surgery, what happens at the time of surgery, what happens when you have uterosacral suspension. I tried to explain each of these with her, but I also -- and she agreed that she had this urgency and frequency and urge incontinence before the surgery.

Her expectations before the index surgery was that it would take care of everything. She didn't understand that there was more than one problem. And also explained why the use of the TVT at that time.

I don't have any criticisms of the surgeries or anything else. I just with this patient tried to provide her information from the American College of OB/GYN and also recommended the AUGS Web site, and the NIH to give her some other things to look at.

Q. All right. Well, let me ask you this: In terms of what you went over with Ms. Daniel, so if I can understand some of what you just said, as I understand, you believe that she -- it looks like

mixed urinary incontinence, which means -- I think what you're saying is she had urge incontinence as well as stress urinary incontinence sort of concurrently at the time that she had the TVT implanted?

A. Yes. She had a mixed incontinences with a primary urgency/frequency component.

Q. And I think what you're saying is the TVT is designed to treat stress urinary incontinence, but not urge incontinence?

A. That is correct.

Q. And is what you're saying that Ms. Daniel is continuing to suffer from urge incontinence, rather than stress urinary incontinence, since she had the TVT implanted?

A. Her biggest complaint is the urge incontinence, yes. On my exam, I could not -- she did not leak with cough or straining. However, I did not fill the -- I don't do any invasive things and fill the bladder or anything with that. But she said that her bladder was full. I had her cough three times, and she did not leak. So I could not demonstrate a positive cough test on that patient both sitting and standing.

Q. So as I understand your opinion, she's continued to suffer from urge incontinence, but not stress urinary incontinence?

A. I could not document the stress urinary incontinence on my exam.

Q. All right. Let me ask you -- if you'll turn to Page 1 of your report.

A. Yes, sir.

Q. All right. Let me ask you just a couple things, and I'll just kind of -- you'll have to bear with me on some of my pronunciations.

On your second paragraph, you write Debra Daniel is a 57-year-old white female and then her birth date, gravida 3 para 1 with a past medical history of -- and I'm just going to start going through these one by one -- over announce disease --

A. That was Raynaud's disease. But yes.

Q. I see what you're saying now. That was the typo. Got it.

A. Yes, sir.

Q. -- hypothyroidism, depression, anxiety, dyspareunia, abdominal pain -- trichomoniasis, is that how you say it?

A. That is correct, sir.

Q. -- yeast vaginitis, constipation, irritable bowel syndrome, hypercholesterolemia, mixed urinary incontinence, cystocele, rectocele, adenomyosis, abnormal uterine bleeding, mixed urinary incontinence, atrophic vaginitis, and splinting with bowel movements.

All right. Let me just ask you about a couple of these that you've listed. Are these the -- is this sort of just a general medical summary, or did you make this list for a particular reason?

A. This was more of here's what's gone on that's documented in the medical record, so it'd be more like a past medical history.

Q. I see.

On just a couple of these, with respect to Ms. Daniel's depression and anxiety, are you going to offer any kind of opinion with respect to her medical -- or for her mental condition?

A. No, I am not.

Q. Okay. With respect to her -- and we talked about the dyspareunia, about the episodic dyspareunia from '97 and then how her dyspareunia is likely a lot different today. You would agree with

that?

A. She hasn't had intercourse because of her husband's medical conditions for several years, but I would pretty much -- she's not sexually active, but I pretty much agree with what you're stating.

Q. Right. All right.

And with respect to her abdominal pain, do you know if her abdominal pain prior to the TVT was episodic or chronic?

A. I believe that she had intermittent episodes of this.

Q. Okay. Do you think that the intermittent episodes of abdominal pain are contributing to any of her alleged injuries from the TVT as of today?

A. If the -- you know, with irritable bowel syndrome, that can cause abdominal pain. That was in her history. Am I saying today that it's a cause? It's definitely a background noise, but she really wasn't complaining of that at the time of my exam.

So I think that that could be a cause for longer-term chronic pain. I cannot state definitively that that is the case, especially since on my IME, palpation of that right side replicated

both of her pains.

Q. All right. With respect to the hypothyroidism, do the think that the hypothyroidism is contributing to any of her injuries she's alleging in this lawsuit today?

A. I do not believe so.

Q. Okay. What about Raynaud's disease?

A. The Raynaud's disease, that is the -- I'm getting out of an area of expertise. I'm having to go back to medical school a little bit.

That is a vascular disease that can be associated with other vascular problems. However, I do not feel that her pelvic pain is associated with that. That would be more extremities.

Q. I see. Okay.

What about her trichomoniasis and yeast vaginitis?

A. The trichomoniasis on that exam was a wet mount, and they didn't -- they felt that she had trichomoniasis, which can be a -- it is a sexually transmitted infection.

But I feel that it was treated and cleared, but we don't have any other things in her medical records reporting positive chlamydia or

anything like this, so I believe that was an episodic episode, and I do not believe it would be contributing.

Q. All right. What about her constipation?

A. Constipation can cause abdominal pain. In fact, just last night, I was called and have a patient being treated in the hospital by the hospitalist because she has not had a bowel movement in three weeks and having significant abdominal pain.

So if somebody is severely constipated -- I think all of us have had one child that we've taken to the emergency room thinking that they were having appendicitis and ended up being constipated.

So constipation can -- she has -- or she does have constipation problems. On my exam, palpation over the rectum, and I did not feel hard stool. I think that that could cause intermittent abdominal pain, but I do not feel it is causing a persistent chronic pain.

Q. Okay. What about her hypercholesterolemia?

A. Her high cholesterol I don't believe is affecting this. However, some of the medications

can cause myalgias. But I do not feel that the hypercholesterolemia is a cause.

Q. What about the -- we talked about the mixed urinary incontinence earlier.

What about the cystocele?

A. This has been -- she had the cystocele before her index surgery, and then she also had a prolapse, and it appears to be addressed. The cuff is well supported. We're not seeing the vaginal walls coming down.

So the cystocele, per se, I think is no longer a problem. However, the surgical procedure correcting the cystocele may be a problem, just the postoperative course, basically.

Q. All right. What about the rectocele?

A. The rectocele, on my examination, I really could not elicit pain posteriorly, and so I do not feel that, one, the rectocele has been addressed, and, two, I could not elicit pain along the rectum at all.

Q. I see.

What about adenomyosis?

A. That was a pathology finding, and her hysterectomy was also for very heavy bleeding, and

adenomyosis can be associated with chronic pain, very heavy bleeding. It is more of a pathology diagnosis. And I believe this would explain her abnormal periods that resulted in the hysterectomy.

Q. I see.

A. Because the hysterectomy -- the uterus has been removed, the adenomyosis is no longer present.

Q. I see.

All right. Well, let me ask you: In terms of -- and then you have kind of a medical chronology of various -- of notable events from her medical records after this, right?

A. Yes, sir.

Q. All right. And I want to turn your attention -- we talked about the December '97 earlier, and I want to turn your attention to the last entry on Page 2.

And you write, on September 13, 2007, she was seen with complaints of low back pain, and she also complained of increased urinary frequency and rated her pain a five out of ten severity. UA was negative. The patient was prescribed ibuprofen 600 milligrams every six hours as needed for the pain.

Do you have an understanding of whether

this was a bout of episodic lower back pain, or was it more of a chronic case of back pain at this point?

A. I believe that this was more of an episodic, and part of the reason I do is that she was prescribed the ibuprofen, which is a nonsteroidal anti-inflammatory, and I believe that that pain -- she may have some underlying things with an exacerbation, but I believe that was more of an acute episode.

Q. All right. Well, this is about, give or take, almost four years prior to her TVT implant, right?

A. That is correct, sir.

Q. Okay. So my question is: With respect to -- she does complain about back pain at this point in 2007.

Have you seen anything in her medical records that would indicate as of today her back pain is contributing directly to the dyspareunia, pelvic pain, and voiding dysfunction?

A. I do not recall seeing any imaging that showed any problems or anything else, and she was not complaining of back pain, and I could not elicit

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back pain on my exam. So at this point, I would say no.
Q. Okay. All right.
Let me just turn your attention -- you talked about briefly Dr. Sze and the decision to go ahead and implant the TVT for stress urinary incontinence, and that was, from my understanding -- I think it was May 16, 2011, correct?
A. I'm flipping through my pages.
Yes, sir.
Q. Page 4, right?
A. Well, the May 16 actually was when the hysterectomy was performed. Her seeing Dr. Sze was March 24, 2011, on Page 3.
Q. Okay. I guess -- I see. March 24, right. Okay. I see. I just misread the May 16 record. Right.
So my question is: With respect to Dr. Sze -- and you don't disagree with the decision to go ahead and implant the TVT product for stress urinary incontinence, correct?
A. That is correct.
Q. From reviewing his operative report and the medical records associated with the

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implantations, do you have any criticism of Dr. Sze's technique in implanting the TVT product in Ms. Daniel?
A. I did note that he did not make a second incision on placing the TVT, and usually we recommend that, but I do not feel it deviated from any standards. I cannot complain about that. It was just something I pointed out.
Q. Well, I mean, it might not, as you say, be a standard-of-care violation, but what I'm asking is: Did anything -- was there anything about Dr. Sze's surgical technique that you feel is contributing to Ms. Daniel's injuries she's claiming today in her lawsuit?
A. When I look at -- well, I typically do not remove much epithelium when I do an A and P repair. I used to, but I've definitely gotten away from that. But I'm not going to critique that. I was not the surgeon present.
But my feeling is if you don't have extreme redundancy of tissue, I try to leave as much behind as I can for remolding. But I do not have any critiques of his technique.
Q. So it's fair to say that there's nothing

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that Dr. Sze did in his implantation surgery that would be contributing to Ms. Daniel's injuries that she's claiming today in her lawsuit?
MR. ROSENBLATT: Object to form.
THE WITNESS: I believe that with a large pelvic reconstruction like this, you need to counsel the patient on the chances of dyspareunia, voiding dysfunction just from the reconstruction and then also discuss with the patient, in doing a TVT, here it is also.
So I've reviewed over his informed consent, which I think was adequate. You know, in talking with the patient, she really, I don't think, had a complete grasp of things because she said, "I've never had anybody explain it to me like this before."
So, you know, I'm not going to -- I don't know Dr. Sze, but I just -- the patient, in talking with her and explaining things and how she thanked me for going over this, I'm not sure she understood everything before surgery.
BY MR. BROWN:
Q. Well, I mean, I understand about before and consent.

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What I'm asking, though: Is there any -- did you see anything about how Dr. Sze put in the TVT product in Ms. Daniel that you think is causing her alleged injuries of dyspareunia, pelvic pain, and voiding dysfunction?
A. No, sir.
Q. Okay. And with respect to the hysterectomy performed by -- I think it's Dr. Hochberg --
A. I'm not sure how to pronounce the name, but I'll go with what you say.
Q. Dr. Hochberg, and that's on -- and you noted it occurred, it looks like, May 16, 2011?
A. Yes, sir.
Q. All right. Do you have any criticism of how Dr. Hochberg performed the hysterectomy for Ms. Daniel?
A. I think he actually supervised it, but the op note, I find no concerns.
Q. So nothing about the hysterectomy technique that you believe is contributing to Ms. Daniel's injuries today?
A. No, sir.
Q. Okay.

MR. BROWN: All right. Let's -- we've been going about an hour. Let's take a quick five-minute break. Okay?

THE WITNESS: All right.

(9:59 a.m. - Recess.)

(At 10:05 a.m., with all parties present as before, the following proceedings were had, to-wit:)

BY MR. BROWN:

Q. Doctor, we've been going over Ms. Daniel's medical history before we took a break. And I'd like to turn your attention to Page 5.

In the entry for May 7, 2015, you note that she saw a Dr. Robert, it looks like, Shapiro?

A. Yes, sir.

Q. Okay. In the last sentence of that paragraph, it states it was noted that she was a good candidate for abdominal sacral colpopexy, and he ordered preoperative urodynamics and cystoscopy before scheduling surgery.

Do you have any reason to disagree that she was a good candidate for an abdominal sacral colpopexy?

A. I believe that that is a surgical decision between the physician and the patient. However, she had had a failed native tissue repair, so I believe this is very appropriate.

Q. Okay. And then ultimately she, it looks like, actually had the procedure done looks like

August -- on the next page of your report, it looks like August 5, 2015?

A. Yes, sir.

Q. Okay. So with respect to the operative findings, I want to ask you about a few of these.

And on your August 5, 2015, note in your report, you note the operative findings for Stage 3 recurrent apical defect. Could you explain what that is to the jury?

A. With this -- and I am going to flip back to the note on May 7. And when you're going down -- and it is about two-thirds of the way through the paragraph -- her POPQ exam showed the anterior wall to be well supported. However, the vaginal cuff came behind the hymen 2 centimeters, as well as point BP plus two.

So BP on the POPQ exam is a spot taken above the opening of the vagina that is a standard mark, and this is basically what I would describe -- think of a sock that you reach through and grab the toe and you're pulling the toe down, and that toe comes down 2 centimeters beyond the opening of the vagina. So when it talks about a Grade 3, it means that that presenting part is beyond 2 centimeters

beyond the opening of the vagina.

But how I like to explain to patients when we see this is exactly what I said, just think of a sock, so that way they get a visual. I try to draw it, but I'm definitely not an artist, and usually I scare the patients when I am drawing. So I try to explain as best I can and then grab a sock, and I actually show them how it happens.

Q. I see.

And then with respect to some of these other things, you noted his operative findings.

Can you explain what a bilateral ureteral patency is?

A. Bilateral ureteral patency means that on cystoscopic examination, you're looking at the opening ureters into the bladder, and you see urine squirting out. We also may give a dye that changes the color, makes it a little easier to see.

But that documents that those tubes from the kidney to the bladder are open, and I would have done exactly that same part. And also Dr. Sze did this also, because with a uterosacral colposuspension, we have to document ureteral patency, because up to 11 percent of the time, you

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can kink a ureter during that procedure, and you have to remove the stitch and replace it.

So what that documents is that the tubes from the kidney to the bladder are open.

Q. I see.

Let me ask you: In terms of the August 5 entry, it looks like the cystoscopy with bilateral ureteral stent placement was done by a Dr. Zaslau, urologist?

A. Yes, sir.

Q. Any criticism of his technique from reviewing the operative report and surgical record?

A. Not at all.

Q. Okay. And, Doctor, I want to kind of move on to the opinions part of your report, which I think starts on Page 6 that we're on. And we've talked about, you know, the differential diagnosis earlier, so I'm trying not to go over that kind of ground again.

So if you'll turn to Page 7. What I want to start with is -- we've talked also about the voiding dysfunction and the dyspareunia earlier, so I kind of want to start with this paragraph that says, "I also consider tissue in growth..." Do you

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see -- are you with me?

A. Yes, sir.

Q. Okay. You write I also consider tissue in growth into the mid-urethral sling mesh, mesh contracture, scarring, polypropylene particle migration, particle loss, roping, curling, fraying, and degradation of the mesh.

You write such claims lack any reliable support based on the hundreds of clinical studies evaluating thousands of women with TVT, as well as the Level 1 RCTs, meta analyses, systematic reviews, and position statements.

So with respect to these conditions that you list in the first paragraph, have you ruled them out completely, or are they just small possibilities?

A. These -- you're talking about the mesh contracture, et cetera; is that --

Q. Right. Right.

A. I do not feel in the literature that this is supported, and so I'm having to base those opinions on the highest grade of evidence available to me.

And I'm aware of some of the studies and

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some of the concerns, but when I'm talking with a patient or when I'm looking at this, what is the best evidence available to look at. When I look at expert opinion, that's the lowest grade. You know, to me, kind of show me what's out there.

And I feel with this that when we look at, say, particle loss, that you have the Periante [phonetic] study, but that is a benchtop study that is designed to distort the mesh material, and that is not intended for use. And when I pull up a PubMed search or something, I really can't find anything. And so when I look at that, I have to look at it a little bit askew.

Also going into the corporate documents where they specifically looked in their submission to the FDA on particle -- I believe it was in rabbits, but I'm not absolutely positive. But they actually specifically looked for particles, and they didn't find them. Now, that's an animal study, but I really don't have a good grade to look at beyond this.

And so with the FDA looking at this and requesting this to be looked at and they did a standardized animal study and they didn't find it,

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there just isn't data out there to support that that is causing a problem.

Q. So I guess this is sort of more of a general opinion, and you're kind of applying it to Ms. Daniel's case specific --

A. I believe that I consider this in any patient that -- literally any patient that I would see whether it's in litigation or when they walk in the door.

I go over all of these things, and I try to explain them to the patients. Here's some of the theories that are out there. Here's what the literature is looking like. There are areas that we need more research in, but here's what we have available today. Because when I'm discussing with a patient, I have to present what is available today.

Q. All right. Well, I'm not here to generally go over your general opinions on TVT.

But I do want to ask: Just on these lists you put in for Ms. Daniel's case-specific report, have you ever concluded that mesh contracture was contributing to an injury in either one of your patients or a case you've testified in?

A. I have not testified that mesh contracture

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has caused pain. I have looked at ultrasounds, the deep study, also the low study looking at ultrasounds and the mesh, does it contract and does it shrink, and those studies do not indicate that the Prolene polypropylene meshes contract or retract.

The other thing is that when we look at longer-term data in studies on retropubic TVT, because that's the most studied, if we were looking at mesh contracture, we would be seeing an increased incidence over time of obstruction or voiding dysfunction, and we just aren't seeing that. And so with that in mind, I feel that mesh contracture would not be leading to her voiding dysfunction.

Scarring -- when I look at any type of surgery, scarring can be present, and on this, scarring around any implant, I did not feel that there was any tenderness in this area, and I just don't feel that scarring was eliciting anything along those lines. On palpation of the trajectory of the mesh, I did not feel banding.

Curling, as I'm aware of it, is when the sling is stretched beyond its normal capacity looking at the edges to see if they curl on end.

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Again, that's not the intended use, and I would not -- I believe that that would have to be something that is explanted, and then there may be controversy on what's fraying and what's curling.

So when I look specifically at TVT and then taking it now down to this case, more likely than not, I do not feel that any of these are causing her pain.

Q. Well, I understand about you don't feel that these are causing Ms. Daniel's pain, but what I'm asking is: Have you observed in your clinical practice or have you testified in another case observing any of these conditions as a cause of pain?

A. Specifically in litigation, I look at these aspects, I consider them, and I do look at the literature.

I do feel that you may have a patient where they do have a point tenderness, whether it is due to tissue in growth into the mesh, which is what it's designed for, you know, in passage of anything, but that could cause a nerve to be irritated.

But usually in my examinations, if I have somebody that has a tenderness, it's usually a point

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tenderness, and I then will try to address that issue or do a trigger-point injection to see if the pain goes away and things along this line.

So I have seen pain. I can't say it is caused by the mesh. And I then look at what is going to be the way to treat it, and the first thing that I always do is conservative therapy.

Q. All right. Well, if you go down just a little bit below in that paragraph on Page 7, you write the literature does not support contracture of mid-urethral slings, and I'm unaware of any studies in the medical literature that document migration of Prolene polypropylene particles causing clinical problems in patients undergoing mid-urethral sling procedures.

So what I'm asking is: Generally do you believe that there is contracture of mesh with respect to the TVT product?

A. With respect to the TVT product, I then have to look at the ultrasound data, and it's not supported.

Q. Right. I'm just trying to -- that's just what I'm trying to make clear.

You just don't believe that phenomenon

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occurs?

A. I believe it's not supported in the literature, and when I'm educating my patients, I have to go on what's available in the literature. Whether I say something or not, that's -- my patients deserve better than that, and so I have to sit back and say, "Here's some of the things that we look at."

And when I do an implant on somebody, I go over each of these preoperatively to try and address any of these issues, and I say, "Here's what the literature says."

So the literature doesn't support it, and I can address theory, but I then have to fall back on the literature.

Q. All right. And if you'll turn to -- it's just the sentence below, and then also you write I am unaware of any literature that shows degradation of Prolene polypropylene occurs in vivo with TVT, or that if it theoretically did occur, that degradation leads to any compromise, clinical significance, or complications from mid-urethral slings.

Is it fair to say that you personally haven't concluded that degradation could be a cause

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of a woman's pain from a TVT mesh product?
A. I believe that when you look at submissions to the FDA, the dog studies that were -- the seven-year dog studies from Ethicon on the Prolene mesh or the Prolene sutures, that degradation probably doesn't occur.
When you look at electromyographs and all, we do know that formalin fixation with protein can cause a proteinaceous coat around there, but the Ong study that's going to be presented at IUGA in August and also run the basic science paper, they showed how when you take a polypropylene mesh and sequentially clean it, that it remains pristine.
And the original study looking at formalin and protein and meshes actually occurred in 1948. And so when these theories were being espoused, I took a course in electron microscopy in college -- so it was a long time ago -- and I used to do IR a long time ago, and something in the back of my mind wasn't clicking. And then with the Tim report on looking at the plaintiffs' allegations actually brought some clarity. It's one of these question marks you have.
And so as I look at this and I look at

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degradation and these things, how much of that truly is artifact, because if a specimen is in formalin before it's processed, it adds something in the processing that would not be in vivo.
So the short answer is I'm not convinced that degradation occurs, and in the dog study, there were a couple areas that may have had minimal degradation, but did not -- it was considered very minimal. And then on multiple people in the dog study, they stated at the end no degradation of the Prolene suture noted.
So there's some controversy in who wrote what. You had multiple people doing things. But the reality is back in the '80s and then going all the way back to the '40s, it just doesn't look like we're seeing this problem. And we do know that if something is in formalin, it creates a proteinaceous binding, an organic binding, that can affect the electron microscopy and affect these things.
So right now I'm not convinced that degradation is a concern.
Q. All right. And that's just both in your -- that's sort of both your general opinion and then the opinion in Ms. Daniel's case, that

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degradation isn't a concern; is that right?
A. I have looked at it. It's part of my differential. But I do not feel in either of these sections that that is the case.
Q. All right. Now we're on Page 8 of your report, and I think this sort of dovetails what you've talked about.
And if you look at the second sentence, it says the limited and recent data suggesting that Prolene polypropylene degrades is unreliable and fails to demonstrate any objective verification of degradation. And then it looks like these are the actual studies that you find are unreliable?
A. In looking specifically at the Clave study, they took 100 samples, but all of these were formalin fixed. So, again, going back to 1948, these are formalin-fixed studies, and the cleaning process is very difficult.
So when I look specifically at that study, I have to discount that there may be either an unintended bias or there's a processing error. And I think that when we compare this and then look at the basic science that Ong is presenting in August at IUGA, I think it will explain those differences.

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And, to me, I had to go back to college and look at things, but it actually is very well documented that if something has the formalin, which is a standard fixative -- that's what we put all our stuff in when we're in the OR -- that it does affect what the material will look like.
Q. Okay. If you move onto your report, there's -- a couple of sentences down, you write I am aware of the animal studies that plaintiffs' experts rely on, but I do not consider that literature to be a reliable assessment of whether TVT shrinks or contracts in vivo because we have more reliable data that has actually studied the product at issue, TVT in women, not dogs or rats.
A couple things about that, do you have a general -- well, strike that.
Do you believe animal studies are reliable at all with respect to analyzing whether TVT shrinks or contracts?
A. I believe that that is part of the process, but what I have to do is I have to go with the highest grade of literature. And so with that in mind, when we look at, you know, randomized control trials, the meta-analysis, the systemic

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reviews -- and that's considered the best data -- it just doesn't support it.

I'm not saying that animal studies are not important, but what I feel very strongly is I have to go to the best literature available. And there are problems with every type of study and everything else, but I have to -- in educating my patients and in formulating opinions, I have to go with the best data, look at the other stuff, try to look at trends, try to make sense of some of these things.

But when it comes down to the bottom line, I have to look at what is the best evidence available. I don't exclude the other evidence, but I have to look at what is the best evidence.

Q. Right.

Well, let me ask you generally -- and when you're talking about plaintiffs' experts, are you talking about the general expert reports for the plaintiffs' experts that they've retained in this litigation?

A. I review over expert reports not only just on the medical aspect, but on the outside whether -- I don't understand it all, I'm trying to get an understanding of this very complex issue, and so I'm

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looking at pathologists, I'm looking at electron micrographs, I'm taking extra time to try and figure these out and look at these arguments.

Also I'm always asking, if this is for abdominal surgery, is that intended use for TVT, and looking at what the concerns are with, you know, abdominal or hernia repairs, are they the same -- are they the same vector forces. They're placed in different environments.

I'm trying to look at all of this, but I have to go back specifically in this case, in the litigation, what is the intended use of the product, what is the intended scenario of the product. So I'm trying to understand the whole picture, but also I'm coming back to intended use.

Q. Let me ask you generally: In terms of the experts in this case, for Debra Daniel's case, do you have -- are you going to offer any opinions specifically rebutting one of the plaintiffs' experts?

A. I believe that if the plaintiffs' experts are stating mesh contracture, particle migration in their concerns, that has to be based on evidence, both what is available in the best literature or the

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best studies, and if they think it's more of a conjecture, it's conjecture or it's theory, and on that, I will sit back and say is that supported in the literature. So in those cases, I may say -- you know, I would opine that it's not supported in the literature, and so --

Q. Well, let me ask just more specifically: Have you -- for Dr. Bruce Rosenzweig, have you read his case-specific report with respect to Debra Daniels?

A. Yes, I have, sir.

Q. All right. Is there any opinion that you see as of today that you know you're going to offer an opinion criticizing or rebutting from Dr. Rosenzweig's case-specific report?

A. I'm going to find his case-specific report, and I'm going to flip through on this, and now I'm on -- one second.

On Page 14, it says as a result of the TVT transvaginal mesh product, including mesh characteristics, discussed subsequent reactions and surgical revisions. Ms. Daniel has sustained injuries that are most likely permanent in nature with pelvic pain, pressure, and dyspareunia.

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On this, when I did my IME, I could exactly replicate her pain, and it was nowhere near the TVT site, and she agreed that that was an exact replication of the pain. So with that, I feel that it's not a result of TVT implantation. It is due to a result of other things. So more likely than not, it is not, and my exam directly supported that.

Then on Paragraph 2, he goes in degradation -- it says here were directly caused by TVT mesh, including degradation of the mesh, chronic inflammation and chronic-formed body reaction, mesh was never meant to be implanted inside the human body, and the mesh was designed to be implanted in the body.

And so when he is -- when I see this statement, is it TVT, is it hernia mesh, is it anything that we use in surgery to augment tissue. Loss of pore size with tension, again, TVT, when you pass it, it is -- you pass it under tension that does not distort the sling.

When we talk about fibrotic bridging and scar plate formation, the mesh is designed for tissue to grow in, and this is supported in the pathology when we look and find blood vessels,

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et cetera, in there.
So I would say these are opinions that do not have great scientific validity in the study area. And her chronic pain, I feel that we were able to elicit directly with that, and certain procedures may be okay.
She really doesn't complain of frequent urinary tract infections. She does have urinary dysfunction, and this was occurring preoperatively, and I believe -- and I told Ms. Daniel that she would be a candidate for other treatment for her urinary urgency and frequency and urgency incontinence, such as neuromodulation. I believe that she definitely has options, also Botox or pretibial nerve stimulation. So I take issue to that.
I at this point cannot see that she needs a mesh revision. I do look at the failure to warn physicians, and I believe on the instructions for use that it is definitely in compliance with federal regulation and that there have been modifications to the IFU from launch to present.
But the federal regulation states what is unique to this procedure, and what's unique to TVT

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versus the other ones is going to be mesh erosion, which has been in there all along. So I would say that when it talks about the instructions for use, I very much disagree with that assumption, and so on that I would disagree.
Q. All right. Well, let me ask you -- and we'll get to the IFU in a sec.
Any other criticisms of Dr. Rosenzweig that you can see that you're going to offer?
A. I believe right at this time -- I may find some, but I'll say at this point, no.
Q. All right. What about -- have you seen the expert report of Erin Carey --
A. Yes, sir.
Q. -- or Dr. Carey, I should say?
A. Yes, sir. Expert report, and I believe she also -- no, she didn't do an IME on this one. I think she did do an IME, and we -- actually, she did because she also found that the vaginal cuff was very tender. Also on her IME, she could not, more likely than not, say that the problems were TVT related. We're looking for it right now. I apologize.
Q. Okay. Well, I'm not -- I'm only asking on

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the case-specific findings for Debra Daniels.
A. Uh-huh.
Q. Do you have any specific criticisms of Dr. Carey's either IME exam or her opinions?
A. Actually, the IME exam I do not have any problem with. And I'm still trying to find her IME. I apologize. Give me just a moment.
Q. Go ahead. Why don't we go off for just a sec while you look for it.
A. Actually, we have just found it.
Q. So we're good. All right.
A. So on her expert report, many times -- and I'm just going to go through here, and on her expert report -- and I'm on Page 2, she talks about --
Q. Doctor?
A. Go ahead.
Q. I'm not trying to cut you off.
I'm not asking about the general opinions. I'm just asking about the case specific for Debra Daniel.
A. Okay.
Q. Go ahead, though.
A. I am going to go to her IME, and she and I very much agreed, except I didn't feel Debra Daniel

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had mild atrophy. She had significant atrophy on her vaginal exam.
And when you look at her plan, she says that Ms. Daniel's primary complaint is de novo voiding dysfunction following the sling implant. That is not in the medical record. It actually -- the patient also stated that it preceded the implant.
So as we look at this, this does not agree to the medical records or to what the patient said in our IME. So on Page 14, Paragraph 2, I am very much in disagreement with this.
Q. Okay.
A. And then on Page 3, she talks about no history of sexual pain prior to her surgery. We did have that isolated episode. There's a conflict in the medical record, and I'm going to have to look at my report -- one second -- on this, because in the medical record, she saw a physician, and it was documented she had not had intercourse.
And this is on Page 3 of mine, Paragraph 2, January 25, 2010. The patient presented to the clinic with complaints of an abnormal uterine bleeding, and I'm going to go down

further. At that time, it was reported that she had not been sexually active for two years, so that was January 25, 2010.

And so it's one of those areas where we have where she's not been sexually active with a husband whose lung capacity is decreasing, and then they're saying that there's no history of sexual pain prior to her surgery. I'm not sure she was sexually active.

In Dr. Rosenzweig's one, he said the patient disagreed with this. But that's what's in the medical records, so I have a little bit of a problem with being able to say there was no history because we have a history she wasn't sexually active.

Now I'm going to go to Paragraph 4. Mild general atrophy, I felt that it was much more than mild, but I feel that the estrogen, just as she recommended, would be a benefit. Recalls her pelvic pain, it's difficult for her to describe, and I think that in her differential, including bladder spasms, I feel that that is not an unreasonable expectation.

On the IBS, it's in the medical record,

but I'm not going to disagree with Paragraph 6. Also the sacroiliac joint tenderness I'm not disagreeing with. I feel that on Paragraph 8 that the lichen sclerosus is definitely a potential, but also very significant atrophy that may just respond to the estrogen.

So in her report, the one I'm most concerned about is that this wasn't -- the bladder dysfunction occurred after the procedure, and actually it was present before.

Q. Okay. I see.

Any other direct disagreements or criticisms at this point in time that you know of?

A. Specifically on the case?

Q. Yeah. I'm just talking about with Dr. Carey.

A. I have some disagreements with some of her general opinions, but her case-specific findings I am fine with.

Q. Okay. All right.

Let me turn your attention -- we talked about the -- you brought up earlier about IFU for the TVT, and obviously that stands for instructions for use, right?

A. Yes. That is correct, sir.

Q. Okay. Well, first of all, are you -- do you consider yourself an expert in the field of warnings for a medical device product?

A. I have worked on instructions for use not only with TVT Secur, but also with LigaSure and also ThermaChoice. So I have been involved in looking at this for much of my career, so I would consider myself much more aware of it than the average physician.

The other thing is I have lectured extensively both nationally and internationally and always recommend that physicians look at the IFU not only on how to do the procedure, but also in going over the federal regulation what is the unique complications that can occur with this, because I think physicians, they are going to be looking at this saying, "Okay. Here's where are the unique complications."

However, on an IFU, I don't necessarily agree that we put everything on there because many things, specifically with TVT, are going to be involved, whether it's TVT or autologous sling or Burch colposuspension. So I stress to physicians in

the past, "Here is what is unique. This is what is required by the U.S. Federal Government." Then we can go over all of the other things that are more what I would call general procedure specific or surgery specific.

Q. Okay. Well, you said a few things there.

With respect to your work on the IFU for the TVT Secur, did you help design it, or did you have input into the contents? I'm just trying to understand what work you did on that IFU for that product.

A. On that -- on the development of the TVT Secur, I was involved in some of the benchtop studies and looking at potential complications. Also in the development, when you're looking at design, defects, safety -- DDSA -- I'm trying to think of what the last word is. I'm sorry with all the acronyms.

But as we were looking and had discussions on what was going to be packaging, what are the things that are acceptable, what are not, how is it improved, so I was involved down the line on that, so looking at what is specific, but then also looking in the packaging aspect, the other things,

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making sure the integrity of the product, which I found to be very interesting and completely out of my normal realm of thought process, so that was an educational experience for me.

Q. Okay. Well, let me ask you this -- and turn to the federal regulations you're citing in your report. Is there a specific federal regulation you're referring to?

A. It is -- I forget the numbers on it, and I'm not good with the acronyms. I will have to --

Q. Well, let me ask you -- go ahead. I'm sorry. I didn't mean to cut you off.

A. It's in the FDA Blue Book guidance, 21 CFR 801.109 C. And so in looking at the Blue Book guidance and also the Ethicon's standard operating procedures and regulatory, legal, and guidance, I've also looked at testimony from the Ethicon's employees.

But specifically when I was talking about the federal regulation, it's the Blue Book and specifically that code, and in that code, it is what is specific to this device.

Q. Okay. So what I'm -- my next question is: When is the first time you reviewed this federal

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regulation?

A. Actually, it would have been -- I'm not sure exactly reading the document, but trying to understand the compliance would have been in the TVT Secur development, and so that would have been, what, 2004 to '06 range, I would say.

On the LigaSure development, those studies and everything were in the late '90s, early 2000s. So reading specifically, I can't say when, but understanding the compliance issues goes back to probably the late 1990s.

Q. So in addition to the -- we talked about the warnings itself with the IFU. Are you considering yourself an expert in the field of regulatory compliance?

A. I feel that -- am I involved on -- in federal regulation and understanding it as somebody would at Ethicon or the FDA? No. Do I understand from my work on federal compliance whether my work with Icon Clinical Research on Phase 1 pharmaceutical studies or developing on products? I do have an understanding more than most.

Q. Well, I understand you have an understanding more than most, but are you

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considering yourself an expert in the field of compliance and federal regulations?

A. I feel that I have more experience than most on that, so from a Daubert principle, I would say -- I would consider myself an expert, yes.

Q. When you say a Daubert principle, I mean, obviously you've been retained as an expert witness in this litigation. Are you considering yourself, I guess, a legal expert in the field of Daubert?

A. I'm not proposing that I am a legal expert on anything. I do have more knowledge than the average person or a juror would have, and that is because I have worked as a clinical investigator in Phase 1 studies for pharmaceutical and also that end-product development in working with individuals that I would consider are the regulatory experts within the industry. And I don't understand all the complexities. However, I do feel I have a reasonable working knowledge of the process.

Q. All right. Let me shift gears and just ask you about another part of your report on Page 8.

A. Yes, sir.

Q. And this is kind of going down kind of near the end of that big paragraph. You write even

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though mesh erosion and exposure are commonly referred to as the only risks of mid-urethral slings compared to other procedures, it is well know that Burch and autologous fascial sling procedures also carry the risk of having a graft or suture erosion or exposure. Do you see where I'm at?

A. One second here. Is it on my --

Q. It's Page 8. It looks like it's the -- it looks like it's the second to last sentence on Page 8, the big paragraph.

MR. ROSENBLATT: He's asking about your report.

THE WITNESS: Oh, here. I apologize. I have things spread out, so I apologize. Yes, sir. Okay. Now I've got it in front of me. What was that again, sir?

BY MR. BROWN:

Q. So the second to last sentence says even though mesh erosion and exposure are commonly referred to as the only unique risks of mid-urethral slings compared to other procedures, it is well known that Burch and autologous facial sling procedures also carry the risk of having a graft or suture erosion or exposure. Do you see that?

A. Yes, sir.
Q. When you say it is well known that the Burch and autologous facial sling procedures also carry the risk of having a graft or suture erosion or exposure, can you explain what the basis is for that part of your report?
A. On this -- whenever you have a suture present that is permanent, you can see an exposure, and it is documented in case studies, you know, and looking at, you know, a bladder years after a Burch, someone develops urgency, and you see a suture in there. So these are reported complications and accepted complications.
Q. So are these things that you've observed in your clinical practice, or is there a particular literature? Or what case studies are you referring to? That's what I'm asking.
A. When we look at autologous slings, we can go to complications. We can look at the AUA guidelines, and we can look at their meta-analysis. So I don't have the AUA paper in front of me, but if we go to their tables, we can look at complication rates and look for that evidence.
But it is also -- as I say in my own

clinical practice, I have seen suture erosions from Burch, because I've been doing Burch for several years, and also we've seen mesh erosions from autologous slings and also other types of slings, such as porcine graft, dura mater.
So the graft erosion you see, suture erosion you see, mesh erosion you see, and so what I'm trying to say is that erosion of the mesh because there's a mesh present is unique to this. However, the other procedures that we do are not without similar-type episodes.
Q. All right. Let me ask you: In terms of the -- I think that's enough for the Page 8 right now.
Just in terms of other materials you've looked at in this case, was there anything of significance in Randy Daniel's deposition that affected your opinions in this matter?
A. I am now looking up Randy Daniel's opinion. Give me one second here. I apologize. I'm looking for it.
MR. ROSENBLATT: Doctor, I think it's on the flash drive, but it would not be included in this binder --

THE WITNESS: Okay. Okay.
MR. ROSENBLATT: -- her husband's testimony.
THE WITNESS: I don't have his testimony in front of me, but I will try to answer as best I can. I don't have it in my binder here.
BY MR. BROWN:
Q. Okay. Well, just as we sit here, are you aware of anything in Mr. Daniel's deposition testimony that's affected your opinions in this case --
MR. ROSENBLATT: Object to form.
BY MR. BROWN:
Q. -- one way or another?
MR. ROSENBLATT: Object to form.
THE WITNESS: I don't have it -- unfortunately I don't have it specifically in front of me. And my recollection is that his COPD has become very significant, along with his taking his antihypertensive medications, on ability to have intercourse. As I say, I don't have it directly in front of me. I'm sorry.
BY MR. BROWN:
Q. All right. Well, what about Dr. -- we

talked about Dr. Sze's operative report and some of his medical records earlier. Was there anything in his deposition testimony that affected your opinions in this matter for Debra Daniel?
A. No. Actually in reviewing over his opinions and -- or not his opinions, but in his deposition, I didn't see anything that I felt I disagreed significantly with. I'm trying to find his deposition now. But I did not find anything that altered my opinion in the case.
Q. Okay. Just give me about one minute. I'm going to look through my notes, and I think I'm ready to pass the witness. So just give me one second here.
Okay. I think I've just got one or two more questions. Are you ready?
A. Yes, sir.
Q. All right. On Page 8 of your report, it's about midway through, you write the Okulu 2013 study is not a reliable study and cannot be directly compared to TVT. Can you explain why you don't think that study reliable, briefly?
A. It is a randomized perspective study. The technique is very different. The surgical procedure

and the description is an entirely different procedure than TVT. I would look at that more as some of the procedures for mid -- or for other -- retropubic sling approach.

The dissection is very different and much more extensive, and the length of the incision covers the urethra and underneath the bladder. So I think that -- in looking at this study, I really can't compare it to TVT. It's a different procedure. I think that it needs to be replicated and looked at further before I can sit back and say is it reproducible, do we have conformation of this. I'm always interested in new techniques, but with this, I have to sit back. After reading it and looking at it, it's not a TVT procedure.

Q. I see.

All right. Shifting gears, with respect to Debra Daniel, are you going to offer any opinion about her long-term prognosis?

A. I am not offering an opinion of her long-term prognosis at this time. I feel that she has other medical options available that she was unaware of, and I am hopeful that if she pursues those, that we can significantly improve her life.

Q. I see.

MR. BROWN: All right. Plaintiff we'll reserve the remainder, and I'll pass the witness at this time.

MR. ROSENBLATT: All right. And, Greg, I'm showing you have about ten minutes left, if you end up needing to use it. Is that what you have?

MR. BROWN: Yeah. I mean, don't -- yeah, at this point, I'm just -- I'm passing it. You can go ahead if you have questions and everything. That's fine. I had about ten minutes on my clock as well.

MR. ROSENBLATT: Okay.

CROSS-EXAMINATION

BY MR. ROSENBLATT:

Q. Doctor, you were asked some questions about the IFU. Do you recall those questions?

A. Yes, sir.

Q. And I believe you mentioned one of the things that you relied on and have previously reviewed was the code of federal regulations, specifically CFR 801.109 C. Do you recall that?

A. Yes, sir.

Q. And the CFR describes how risks that are commonly known to practitioners licensed by law do not need to be included in the IFU. Is that basically your understanding?

A. Yes, sir.

Q. And you've read that in context along with the Blue Book and Ethicon's SOP; is that correct?

A. Yes, sir.

Q. And I believe you were describing your experience where you've actually consulted with a company to help them with their instructions for use?

A. Yes, sir.

Q. And specifically I think you mentioned a LigaSure device and the TVT Secur device?

A. It's LigaSure, L-I-G-A-S-U-R-E. It's a vessel sealing device. And I was one of the first people to use it on vaginal hysterectomies and then in a development of their smaller plan for thyroid surgical Precise starting off on the animal lab level.

Q. And when Ethicon was consulting you on the TVT Secur IFU, would you have voiced your concern if you felt like there were risks that were not

commonly known that should be in the IFU?

A. Yes.

MR. BROWN: Object to form.

BY MR. ROSENBLATT:

Q. Okay. Doctor, you were asked some questions about dyspareunia and your differential diagnosis. Do you recall that?

A. Yes, sir.

Q. Do you recall whether or not Ms. Daniel was sexually active prior to her TVT surgery?

A. I have in the medical record --

MR. BROWN: Objection.

THE WITNESS: -- that she had not been sexually active for two years, and that was in 2010.

MR. ROSENBLATT: Can I get some exhibits? Is that possible? I think we're on Exhibit 4.

COURT REPORTER: Three.

MR. ROSENBLATT: Three.

(Exhibit No. 3 marked for identification.)

MR. BROWN: Hello?

MR. ROSENBLATT: Yeah, still here.

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BY MR. ROSENBLATT:
Q. I'm just going to mark -- or hand you what I've marked as Exhibit 3.
Would this be the medical record that you were referring to?
A. Yes, sir.
Q. And what does this state about whether or not she was sexually active prior to the surgery?
A. The date --
MR. BROWN: Objection.
THE WITNESS: The encounter date was January 25, 2010, and in the HPI, it states not sexually active for two years, and this was electronically signed by Kelly McBee, PA-C, on January 25, 2010, at 16:09 hours.
BY MR. ROSENBLATT:
Q. And then looking at your exam notes from your IME that you performed on Ms. Daniel, did you have her fill out a questionnaire?
A. Yes. We had her fill out a questionnaire.
Q. And did she indicate on that questionnaire whether or not she was sexually active when you saw her in June of 2016?
A. On the intake form, she marks no.

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Q. And on the intake form under female genital urinary section, did she circle whether or not she was having pelvic pain?
A. No, she did not.
Q. But she did circle that she was having painful intercourse, even though she noted that she was not having intercourse. Is that fair?
A. That is correct.
Q. And were you able to elicit any type of other pelvic pain, other than the area that you previously described?
A. That directly replicated her pain.
Q. And looking at Dr. Carey's IME notes, was the area that you described consistent or inconsistent with the area that Dr. Carey noted?
A. This is on Page 11 of Dr. Carey's report, and it says here under speculum -- well, actually, I'm going to go -- well, to the speculum, it says pain upon opening speculum, tenderness of cuff to Q-tip right greater than left, no evidence of mesh exposure, negative Q-Tip exam on the vaginal side walls, and I would definitely agree with that. On the exam -- vaginal exam of right apex is tender, and I did not elicit adnexal tenderness on the left,

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but I would agree with that exam.
Q. Okay. Now, Doctor, I believe Ms. Daniel's medical records do have some reference to intermittent pelvic pain. Do you recall if that would have been before or after Dr. Zaslau's surgery performing an abdominal sacral colpopexy with a wide mesh?
A. I think Dr. Shapiro did the wide mesh.
Q. Okay.
A. And she was having some intermittent pelvic pain postoperatively, and I don't see any listed at that time.
Q. And you also didn't note any additional pelvic pain during your IME, is that fair, other than the area where you --
A. Very point specific.
Q. And that --
MR. BROWN: Object to form on that last one.
BY MR. ROSENBLATT:
Q. And that point specific, was that anywhere near where the TVT sling would be placed?
A. No.
MR. BROWN: Object to form.

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BY MR. ROSENBLATT:
Q. Dr. Rosenzweig notes that there was some vaginal shortening and scarring. Would you attribute any vaginal shortening to the TVT?
A. No, I would not.
Q. And preoperatively is it your understanding that Ms. Daniel had pelvic organ prolapse, mixed urinary incontinence, and atrophic vaginitis?
A. Yes. I'm going to have to look at his report on -- I'm now looking -- yes, and it did discuss atrophic vaginitis at that time of her preoperative evaluation.
Q. Doctor, do you believe that TVT caused Ms. Daniel's urinary urgency or frequency?
A. She had urinary urgency and frequency preoperatively. She had it postoperatively. She has aged. And I do not feel that the TVT caused it because it was a preexisting condition.
Q. And I believe you mentioned urge incontinence as a potential complication of any procedure, as well as a naturally occurring phenomenon with time and menopause. Is that fair?
A. That is correct.

Q. Are you aware of medical records after her TVT implant where physicians noted a zero postvoid residual?
A. Yes, sir.
Q. And what would that indicate to you?
A. There's no urinary retention.
Q. And were you able to assess any urinary retention during your exam?
A. I did not do a postvoid residual inspection.
Q. But do you know if there are -- well, let me -- I believe July -- on Page 6 of your report, July 10, 2015, there was a postvoid residual exam done showing 0 milliliters?
A. That is correct.
Q. So in 2015, based on objective findings, do you have an opinion as to whether or not Ms. Daniel was experiencing urinary retention?
A. By the urodynamics, she was not having urinary retention. She does not have -- she has a zero postvoid residual.
Q. And during your IME with Ms. Daniel, I believe you performed a cough stress test?
A. I did not fill her bladder. I asked her

if she felt her bladder was full. She said yes. I had her cough three times both sitting and standing and no leak was noted.
Q. And so would that indicate to you -- well, strike that.
What does that indicate to you as to whether or not the TVT was performing as intended?
A. She did not leak with stress, so the coughing is a cough stress test.
Q. Do you recall from Dr. Rosenzweig's and Dr. Erin Carey's testimony whether or not they were able to note any particle loss, contracture, scarring, roping, fraying, or curling in Ms. Daniel?
A. They did not.
Q. And, Doctor, you were asked some questions about the Clave study. I don't have a hard copy with me.
But if I pull it up, do you recall what the Clave study found about any objective findings of degradation?
A. I am referring now to -- I believe it's Page 266 -- on the Clave study on the publication, and it states several hypotheses concerning the degradation of polypropylene are described below.

None of these, particularly direct oxidation, could be confirmed in this study.
Q. And I believe the other study that you reference in your case-specific report was de Tayrac and Letouzey in 2011. And, again, I've pulled up that study for you to reference.
What did those authors find in 2011 about whether or not polypropylene mesh was degrading?
A. On this study, after washing with the MSO and ultrasonic shock, it appears that the marked modifications and the mesh surface corresponded to a bio film, and after the bio film was removed, no polymer degradation was seen anymore.
Q. Have you seen any studies that would suggest any clinical consequence to in vivo degradation if it did occur?
A. I am unaware of any studies that show that.
Q. And, Doctor, when you're practicing evidence-based medicine and you're comparing a clinical study to an animal study, why is it that you feel that the clinical study provides better evidence than an animal study?
A. On the grade system, which is levels of

the evidence, the studies done on the humans and the randomized control studies are higher-level evidence or better evidence than the animal studies. So I don't negate the animal studies, but if there's a higher level of evidence available, I look at that.
Q. So would it be fair to say that when you're first testing a hypothesis, you may start with an animal study, but you would continue to study and look at what the clinical evidence shows?
A. Yes.
Q. Almost done here.
Doctor, did you see any records or any findings during your exam as to whether or not Ms. Daniel had a mesh erosion or exposure?
A. There was no evidence of mesh erosion on my exam, and the other physicians in the medical record did not show any evidence of mesh erosion.
Q. Do you have an opinion to a reasonable decree of medical certainty as to whether or not the complaints Ms. Daniel raises in this lawsuit are in any way connected to the TVT?
A. I do not believe --
MR. BROWN: Object to form.
THE WITNESS: I do not believe her

complaints are related to the TVT, and when the patient asked me directly, I told her as such.
BY MR. ROSENBLATT:
Q. And I noticed on the intake form that Ms. Daniel filled out during your IME -- let's see if I can pull it up here -- for the surgery that she said she had, she indicates mesh implant, May 2011. Was the TVT the only procedure that she had in May of 2011?
A. No. That she had a pelvic reconstruction at the same time.
Q. And were those concomitant procedures important to you in performing your differential diagnosis?
A. Absolutely.
Q. And have all of the opinions that you've held in your case-specific report and here today been to a reasonable degree of medical certainty?
A. Yes, sir.
Q. The last thing I want to do is just mark your general expert report as Exhibit 4.
(Exhibit No. 4 marked for identification.)

BY MR. ROSENBLATT:
Q. Doctor, I've handed you Exhibit 4, which is your expert report submitted June 15, 2016. Do you see that?
A. Yes.
Q. Would you also in forming your opinions rely on the opinions that you've offered in your general report?
A. Yes, sir.
Q. Okay.
MR. ROSENBLATT: No further questions.
MR. BROWN: Doctor, I just have one quick question.
THE WITNESS: Yes.
REDIRECT EXAMINATION
BY MR. BROWN:
Q. I understand -- even though you provided a list of materials you've relied on for your report, is there any information that at this time you haven't reviewed or is missing that may affect your opinions in this case, that you're waiting to review?
A. Not at this time, sir.

Q. All right.
MR. BROWN: I'll reserve the remainder. No further questions at this time.
COURT REPORTER: I just have a quick note, Greg. I want to make sure it's on the record. I did bring a flash drive with the case-specific reliance materials, and I just wanted to see if you were going to mark that as an exhibit.
MR. BROWN: Yeah, that's fine. We can mark it as Exhibit 4. That's fine.
MR. ROSENBLATT: I think that'll be Exhibit 5.
MR. BROWN: Oh, okay. Five, then.
(Exhibit No. 5 marked for identification.)
(Discussion had off the record.)
MR. ROSENBLATT: Mr. Brown, just so I can get this on the record, I was informed that you wanted a rough draft and a three-day rush of this transcript; is that correct?
MR. BROWN: That's correct.
(11:18 a.m. - Adjournment.)
** ** ** **

C E R T I F I C A T E

STATE OF NEBRASKA)
)
COUNTY OF DOUGLAS)

I, Chelsey A. Horak, Court Reporter, General Notary Public within and for the State of Nebraska, do hereby certify that the foregoing testimony of MICHAEL WOODS, M.D., was taken by me in shorthand and thereafter reduced to typewriting by use of Computer-Aided Transcription, and the foregoing ninety-five (95) pages contain a full, true, and correct transcription of all the testimony of said witness, to the best of my ability;

That I am not a kin or in any way associated with any of the parties to said cause of action, or their counsel, and that I am not interested in the event thereof.

IN WITNESS WHEREOF, I hereunto affix my signature and seal this 2nd day of August, 2016.

_____
CHELSEY A. HORAK
GENERAL NOTARY PUBLIC

My Commission Expires: October 12, 2016